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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,324	07/08/2003	Norikazu Ueyama	OKA-0209	7360

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WASHINGTON, DC 20036

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/614,324	Applicant(s) UEYAMA ET AL.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/29/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response and amendments filed 29 December 2006 to Office Action mailed 31 July 2006 is acknowledged and entered.
2. Incorporation of application identifiers (e.g., U.S. Nonprovisional application number, Filing date for said application, Attorney Docket Number, Inventors name, Art Unit at the USPTO and Examiner Name) in the header of each page of response filed 29 December 2006 is deeply appreciated.
3. In view of remarks and amendments filed 29 December 2006, objection to the Specification in the Office Action mailed 31 July 2006 is hereby withdrawn.
4. In view of remarks and amendment filed 29 December 2006 indefiniteness rejection to Claims 1-5 and 7-20 under 35 U.S.C. §112, second paragraph in the Office Action mailed 31 July 2006 is hereby withdrawn.
5. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/614, 324), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

CLAIMS STATUS

6. Claim 6 remains canceled.
7. Claims 1-2, 7-8, 11-12, 16-17, 19 and 21 have been amended.
8. Claims 1-5 and 7-21 are pending and are examined on merits.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 16 and 21 remain rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Recitation "derivative" in Claim 21 renders said claim unclear as well as confusing and therefore indefinite because this term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e., the term does not define the metes and bounds of the claimed subject matter.

12. In response to rejections made under 35 U.S.C. § 112, 2nd paragraph to Claim 21 in the Office Action mailed 31 July 2006, applicants, argue that "the Examiner might argue that the amendment does not clarify the similarities between the derivative and the base compound. Applicants believe that in view of the other claim limitations the metes and bounds for the term "derivative" is clear when read in context". Applicants further argue that additionally, "the phrase *derivative of said metal complex* is not indefinite in terms of its scope". Citing case laws, applicants argue that "if the scope for the subject matter embraced by the claims is clear, and if Applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph"

Applicants have made the claim a little clearer than the originally presented claim because of the explanation given for the term "derivative". Nevertheless, there is no distinctive recitation (e.g., a recitation regarding closeness or distinctness of the base compound structure, formulae, molecular weight and other physical or chemical properties with the "derivative". Consequently the metes and bounds for the term "derivative" are still not clearly defined in the claim language as currently presented.

Applicants' arguments filed 29 December 2006 regarding the rejection to Claim 21 in the Office Action mailed 31 July 2006 have been fully and carefully considered but are not persuasive for the reasons of record at page 6, item 11 in the Office Action mailed 31 July 2006 and for the reasons discussed *supra*.

Claim Rejections Under 35 U.S.C. § 103(a)

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-5 and 7-21 are rejected under 35 U.S.C. § 103 (a) as obvious over the combined teachings from Gariepy (WO 93/23425, hereinafter, Gariepy) in view of Anderson et al. (U.S. Patent 5,439,839, hereinafter, Anderson et al.) and further in view of Liao et al. (Journal of American Society for Mass Spectrometry, Volume 8, Pages 501-509, 1997, hereinafter Liao).

In response to rejections to claims 1-5 and 7-21 under 35 U.S.C. § 103 (a) cited *supra* in Office Action mailed 31 July 2006, applicants argue that applicants' invention is drawn to "the development of a rapid and highly sensitive method for determining the amino acid sequence of a protein or peptide through mass spectrometry. Combination of the prior art cited by the Examiner does not recognize this "result-effective" capability of the claimed invention parameters (i.e., novel metal complex having a functional group which has a property of forming a covalent bond". Furthermore, reciting the criteria for establishing a *prima facie* case of obviousness, Applicants conclude that in their opinion, the Examiner has not established the motivation to modify the composition of. Primary reference with secondary references. In other words, applicants are of the opinion that the examiner-cites references either alone or in combination, neither provide a motivation to combine the three references nor make applicants' claimed invention in Claims 1-5 and 7-21 patentably obvious under 35 U.S.C. § 103 (a) over the combined teachings from Gariepy, Anderson et al., and Liao et al.

First of all applicants arguments are drawn to a subject matter that is not presently claimed, within the language of claims as currently presented because nowhere within the four corners of Claims 1-5 and 7-21 there is the phrase, "a rapid and highly sensitive method for determining the amino acid sequence of a protein or peptide through mass spectrometry". While applicants might believe that to be the precise description of their invention, said description is not claimed and since the invention is manifested through the claim language, applicants are arguing about an unclaimed invention.

Turning now to the applicants comments regarding patentably unobvious ness of their claimed invention over the Examiner-cited prior art references:

Regarding Claims 1-5, 7-13 and 17-20:

- each of Gariepy and Anderson et al., respectively teach the instantly claimed metal complexes formed with a carboxylic group or amino group of a protein or peptide encompassing each of the elements claimed in instantly presented Claims 1-13 and 17-20 (See Page 4, Bullets i-iv and Page 5, Bullets v-ix of the Office Action mailed 31 July 2006; Abstract and Column 8, Lines 9-21 of Anderson et al. reference);

- Anderson et al. additionally teach a reagent composition comprising said metal complex (see Bullet ix at Page 5 of the Office Action mailed 31 July 2006);
- Note that Claims 1-5, 7-13 and 17-20 are drawn to a composition and each of the elements claimed in said claims are encompassed in the referenced prior art teachings as demonstrated above.

Regarding Claims 14, 16 and 21:

- Claims are drawn to a method to determine the sequence of a protein or peptide, wherein the metal complex composition claimed in Claims 1-5, 7-13 and 17-20 is applied;
- Anderson et al. additionally teach a method to determine amino acid sequence applying the composition that Anderson et al. describe (See Bullet x at Page 5 and additionally bullets v-ix at page 5 of the Office Action mailed 31 July 2006); and
- Liao et al. teach a method in which charged group is attached to N-terminus of a peptide and said determination of peptide structure is made by MALDI spectrometry.

Thus, each of the three reference recited above and at pages 3-5 of the Office Action mailed 31 July 2006 clearly encompass each of the elements of the composition (i.e., the metal complex) and the method (i.e., to determine the sequence of a peptide by the same identifying step, i.e., Spectrometry) as is claimed in presented language of instantly presented claims 1-5 and 7-21, wherein Claims 1-5, 7-13 and 17-20 are drawn to said composition and Claims 14, 16 and 21 are drawn to said method. Therefore the claimed invention presented in instant Claims 1-5 and 7-21 is *prima facie* patentably obvious over the Examiner-cited prior art references, wherein the motivation to combine said references is within the references because said references teach different aspects/steps of the claimed invention at the time that the said invention was invented. Since as demonstrated in the discussion *supra* the claimed invention is *prima facie* obvious over the Examiner-cited references as a consequence, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was

made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Also, note that although each of the Examiner-cited references by themselves may not teach every component in the same order or manner as claimed in the claims under prosecution in the instant application, these references are not relied upon exclusively but in combination. Furthermore, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or describe Applicants' invention, but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the invention was made.

15, Applicant s' arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Pages 3-6 of the Office Action mailed 31 July 2006 and further for the reasons explained in the preceding paragraph.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at Pages 6-8, item 14 of the Office Action mailed 09 August 2006 and for additional reasons as discussed *supra*. Furthermore, a rejection under 35 U.S.C. §103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

CONCLUSION

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH


shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. For the aforementioned reasons, no claims are allowed.

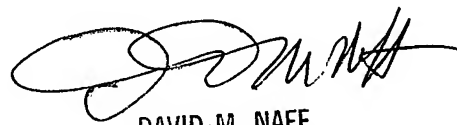
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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March 31, 2007


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/1657